Date of Approval: May 21, 2004

FREEDOM OF INFORMATION SUMMARY

Original Abbreviated New Animal Drug Application

ANADA 200-372

HAN-PEN
(Penicillin G Potassium)

Soluble Powder

For the treatment of erysipelas in turkeys caused by *Erysipelothrix rhusiopathiae*.

Sponsored by:
G.C. Hanford Manufacturing Co.

FREEDOM OF INFORMATION SUMMARY

1. *General Information:*

a. File Number:	ANADA 200-372
b. Sponsor:	G.C. Hanford Manufacturing Co. P.O. Box 1017 Syracuse, NY 13201 Drug Labeler Code: 010515
c. Established Name:	Penicillin G potassium
d. Proprietary Name:	HAN-PEN
e. Dosage Form:	Soluble powder
f. How Supplied:	313 gram/(11 ounces) foil bags
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	0.500 billion units penicillin G potassium/foil bag
i. Route of Administration:	Oral
j. Species/Class:	Turkeys
k. Recommended Dosage:	Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days.
l. Pharmacological Category:	Antibacterial
m. Indications:	For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae* in turkeys.
n. Pioneer Product:	Penicillin G Potassium, USP; NADA 55-060; Fort Dodge Animal Health

2. *TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:*

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and

effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product, G.C.Hanford was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product HAN-PEN, Penicillin G Potassium, USP. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, Penicillin G Potassium, USP, the subject of Fort Dodge Animal Health's NADA 055-060, was approved on December 18, 1983.

3. ***HUMAN SAFETY:***

• Tolerances for Residues

The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.01 ppm is established for penicillin and the salts of penicillin residues in the uncooked edible tissues of turkeys under 21 CFR 556.510.

• Withdrawal Time

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time is one day.

• Regulatory Method for Residues

The analytical method for the detection of penicillin in tissues is a microbiological assay procedure. This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. ***AGENCY CONCLUSIONS***:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that HAN-PEN (penicillin G potassium, USP), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. *ATTACHMENTS:*

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-372:
Foil bag 313 grams (11 oz) and Pail containing 8 11-oz foil bags

Pioneer Labeling for NADA 055-060:
Foil bag (foil pouch)-313 grams (11oz) and Pail containing 8 11-oz foil bags